

β -subunit: (SEQ ID NO:13)

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63. A formulation comprising a FSH variant, containing an alpha and beta subunit, with a preservative selected from the group consisting of phenol, m-cresol, p-cresol, o-cresol, chlorocresol, benzyl alcohol, alkylparaben (methyl, ethyl, propyl, butyl and the like), benzalkonium chloride, benzethonium chloride, sodium dehydroacetate and thimerosal, or mixtures thereof in an aqueous diluent.

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67. A formulation of Claim 63, further comprising a physiologically acceptable buffer.

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70. A formulation of Claim 63 or 68, wherein a

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~~β-subunit~~: (SEQ ID NO:11)

(g): α -subunit: (SEQ ID NO:5)

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β -subunit: (SEQ ID NO:12)

NSCELTNITIAIEKEECRFCISINTTWCAGYCYTRDLVYKDPARPKIQKTCTFKEL
VYETVRVPGCAHHADSLYTPVATQCHCGKCDSDSTDCTVRGLGPSYCSFGEM

(h) : α -subunit: (SEQ ID NO:5)

APDVQDCPECTLQENPFFSQPGAPILQCMGCCFSRAYPTPLRSKKTMLVQKNVTSE
STCCVAKSYNRVTVMGGFKVENHTACHCSTCYHKS

β -subunit: (SEQ ID NO: 13)

NSCELTNITIAIEKEECRFCSINTTWCAGYCYTRDLVYKDPARPKIQKTCTFKEL
VYETVRVPGCAHHADSLYTVPVATQCHCGKCDSDSTDCTVRGLGPSYCSFGEMK

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71. A method of treating infertility which comprises administering to a patient in need thereof a formulation according to Claim 62, 63, or 70.

72. A method of Claim 71, wherein said patient is selected from the group consisting of a human, sheep, cow, pig, horse, or rabbit.

73. A process for preparing a preserved solution formulation of a FSH variant, containing an alpha and beta subunit, which comprises admixing said FSH variant and a preservative selected from the group consisting of phenol, m-cresol, p-cresol, o-cresol, chlorocresol, benzyl alcohol, alkylparaben (methyl, ethyl, propyl, butyl and the like), benzalkonium chloride, benzethonium chloride, sodium dehydroacetate and thimerosal, or mixtures thereof, in an aqueous diluent.

74. An article of manufacture comprising a FSH variant in a container.

75. The article of manufacture of Claim 74, wherein said container is a glass container.

5 76. The article of manufacture of Claim 74, wherein said container is a blister pack.

77. The article of manufacture of Claim 74, wherein said container is a pen-injector device.

10 78. A method of treating infertility in a patient, which comprises administering to a patient in need thereof a preserved solution of a FSH variant, containing an alpha and beta subunit, said solution being suitable for administration over a period of 24 hours or greater.

15 79. A formulation comprising a first vial containing a a FSH variant containing an alpha and beta subunit, and a second vial containing phosphate buffer containing saline or a salt.

20 80. A process for preparing a stable solution formulation of a FSH variant, containing an alpha and beta subunit, which comprises admixing a FSH variant with a phosphate buffer containing saline or a salt.

81. Use of a formulation of claim 62 or 63 for treating infertility in a patient in need thereof.

25 82. Use of a formulation of claim 62 or 63 wherein said patient is selected from the group consisting of a human, sheep, cow, pig, horse, or rabbit.

30 83. A process of producing a formulation comprising admixing a FSH variant, containing an alpha and beta subunit, and a preservative selected from the group consisting of phenol, m-cresol, p-cresol, o-cresol, chlorocresol, benzyl alcohol, alkylparaben (methyl, ethyl, propyl, butyl and the like), benzalkonium chloride, benzethonium chloride, sodium dehydroacetate and thimerosal, or mixtures thereof in an aqueous diluent.

35 84. A process of producing a stable formulation comprising admixing at least a FSH variant, containing an

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alpha and beta subunit, and a phosphate buffer containing saline or a salt.

85. A process of Claim 83, wherein the preservative is phenol, m-cresol, chlorocresol, or a mixture thereof.

86. A process according to any of Claims 83-84, wherein the concentration of FSH or a FSH variant is about 1.0 µg/ml to about 50 mg/ml.

87. A process according to any of Claims 83-84, further admixing an isotonicity agent.

88. A process of Claim 83-84, further admixing a physiologically acceptable buffer.

89. A process comprising preparing a FSH variant lyophilized in a first vial, and preparing a second vial containing a preservative selected from the group consisting of phenol, m-cresol, p-cresol, o-cresol, chlorocresol, benzyl alcohol, alkylparaben (methyl, ethyl, propyl, butyl and the like), benzalkonium chloride, benzethonium chloride, sodium dehydroacetate and thimerosal, or mixtures thereof in an aqueous diluent.

90. A process of Claim 89, wherein said FSH or a FSH variant and preservative are further put into solution.

91. A process according to any of claims 84-85, wherein FSH variant is at least one compound selected from the group consisting of:

(f):α-subunit:(SEQ ID NO:5)

APDVQDCPECTLQENPFFSQPGAPILQCMGCCFSRAYPTPLRSKKTMLVQKNVTSE
STCCVAKSYNRVTVMGGFKVENHTACHCSTCYHKS

β-subunit:(SEQ ID NO:11)

NSCELTNITIAIEKEECRFCISINTTWCAGYCYTRDLVYKDPARPKIQKTCTFKEL
VYETVRVPGCAHHADSLYTPVATQCHCGKCDSDSTDCTVRGLGPSYCSFGE

(g):α-subunit:(SEQ ID NO:5)

APDVQDCPECTLQENPFFSQPGAPILQCMGCCFSRAYPTPLRSKKTMLVQKNVTSE
STCCVAKSYNRVTVMGGFKVENHTACHCSTCYHKS

β-subunit:(SEQ ID NO:12)

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NSCELTNITIAIEKEECRFCISINTTWCAGYCYTRDLVYKDPARPKIQKTCTFKEL
VYETVRVPGCAHHADSLYTYPVATQCHCGKCDSDSTDCTVRGLGPSYCSFGEM

(h): α -subunit:(SEQ ID NO:5)

APDVQDCPECTLQENPFFSQPGAHLQCMGCCFSRAYPTPLRSKKTMLVQKNVTSE
STCCVAKSYNRVTVMGGFKVENHTASHCSTCYHKS

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β -subunit:(SEQ ID NO:13)

NSCELTNITIAIEKEECRFCISINTTWCAGYCYTRDLVYKDPARPKIQKTCTFKEL
VYETVRVPGCAHHADSLYTYPVATQCHCGKCDSDSTDCTVRGLGPSYCSFGEMK

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